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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,382

12/29/2004

Alain Sanson

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

04/29/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/518,382	<b>Applicant(s)</b> SANSON ET AL.	
	<b>Examiner</b> ANISH GUPTA	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,21-23,26-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 34 is/are allowed.
- 6) ☐ Claim(s) 1, 4-11, 21-23, 26-29, 31-33, 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. The amendment filed, 1/21/10, is acknowledged. Claims 1 was amended and claim 30 was canceled. Claim 34-35 were added. Claims 1, 4-11, 21-23, 26-29 and 31-35 are pending in this Application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5-11, 21-23, 26-28 and 30-33 remain and new claim 35 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended from J represents amino acids to all the J variables defined by specific amino acids. Thus, now J26 is defined as Leu, Val or Ile, J64 as Phe, Leu or Met, etc. . . New claim defines all of the J variables with specific amino acids in each J variable position. This amendment to the claims constitutes new matter.

### **Lack of Literal Support**

The originally filed disclosure discloses J an natural amino acids, "in such a manner that at least 50% of them are polar residues chosen from Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, and Tyr (see page 11). Furthermore, the specification state that all J's can be chosen from Ala, Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Ile, Leu, Lys, Met, Orn, PHe, Pro, Ser, Thr, Trp,

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Tyr, and Val (see page 15 of the specification). However the specification does not specifically recite that J 26, for example, is only Leu, Val, Ile. There is no literal support for the specific J variables as claimed in claim 1 and new claim 30.

### **Lack of Inherent Support**

“While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” MPEP 2163. The originally filed disclosure does not provide either implicit or inherent support for the new limitations. There is no guidance within the specification that J variable have specific amino acid substitutions as now currently claimed. The specification generally teaches that J variables are surface amino acids or residues of this peptide when it is in the folded and active conformation. However this does not lead on of ordinary skill in the art to envision that J are very specific residues as currently claimed. The specification only describes the J's in a general manner without any specificity with respect specific amino acid at any given J position.

The specific example and species also do not provide any implicit or inherent support for the markush for the J variables as now claimed. The specification discloses fourteen specific amino acid sequences. These fourteen amino acid sequences do not adequately represent the variability of the claimed genus. For example, the claimed invention states that variable J74 can be Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, Tyr. However, the none of the examples have amino acids that contain a Cys, Lys, Pro or Orn, for example, in position J74. This is also true of other positions within the markush. Furthermore, the species do not provide support for all of the differing combinations of the J variables. There are no species that have Orn in more than one J

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position. For that matter, there are no species that contain a single Orn residue in any position.

Thus, the claims for provide implicit support for the new markush group.

### **Applicants Arguments**

Applicants agree that J amino acids are surface amino acid when it is in a folded and active conformation. Applicant's justification to narrow the scope of the J is that they have compared the sequence of SEQ ID NO: 1-14 and the J variables based on the presence of specific amino acids in the different J locations. Applicants recite the specific J variables in a table for all of the sequences. Applicants make reference to a Venn diagram to establish the relationship of the 20 naturally occurring amino acids.

Applicants argument have been fully considered but have not been found persuasive.

As stated above, this newly crafted sub-genus has not been adequately supported by the originally filed specification. Similar issues have been addressed by the Federal Circuit. For example, in In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), the Court rejected a claim to species that fell within a large genus. The Court analogized the genus of the compounds to a forest and the species to a tree. The Court stated “[i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.” Ruschig, 154 USPQ at 122. Similarly, in Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895, the Federal Circuit declined to find support for a sub-genus based on the disclosure of a genus because the application did not contain “blazemarks” to support the subgenus. In justification for denying support, the Court stated that “just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for

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every species or sub-genus that chooses that moiety.” Fujikawa, 39 USPQ2d at 1905. Thus, it is clear from these decisions that the specification must provide blazemarks to the new sub-genus or species.

Here, Applicants have stated that they reviewed SEQ ID NO 1-14 and arrived at the specific J variables because each J variable as recited occurred in at least one sequence of SEQ ID NO 14. However this does not establish written description for the claimed sub-genus. The new sub-genus contains hundreds of sequences beyond those of SEQ ID NO 1-14. For example, the new sub-genus is inclusive of species where J1 is His, J2 is Gly, J3 is Asn, J4 is Val. None of the 14 amino acid taught in the specification contain a sequence HGNV as the first four amino acids within the sequence. In fact only one sequence contains a Histidine residue as the first amino acid and this sequence does not contain a Gly as the second residue, Asp or Ser in the third residue. Yet all of these sequences are encompassed by the claims. The specification does not provide any “blaze mark” that would lead one to conclude that the genus taught in the originally filed claims would be inclusive of the sub genus now claimed. Moreover, the mere fact that the specification contains specific sequence that contain specific amino acid in certain J positions does not lead to possession of any peptide contain those amino acids. As stated above, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. The specification does not mention Venn diagrams or implies the use of Venn diagrams that would lead one to conclude that the amino acid substitutions are grouped into different Sub Groups. The specification simply fails to provide support for the claimed sub-genus.

The rejection is maintained.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 4, 29, 30-33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims recite specific amino acid sequences that depend from claim 1. However, these sequences do not comply with the markush group of claim 1. For example, claim 1 states that J26 is selected from Leu, Val and Ile, thereby implying that J26 can only be Leu, Val or Ile.

However, SEQ ID NO 11-14 all contain other amino acids than Leu, Val or Ile. SEQ ID NO 11-12 contains Glu, SEQ ID 13 contains a Gly and SEQ ID 14 contains a Met. This is also true of variable J64. SEQ ID 12 does not contain a Arg residue in position 37. Thus, read properly claim 4 does not properly depend on claim 1, since claim 4 contains sequences that do not comply with the Markush Group of claim 1. Applicants are requested to review all of the Sequences claimed to see if they comply with the amended claims.

### **Applicants Arguments**

Applicants argue that they have provided a table that depicts the various J residues of PI in the context of SEQ ID NO. The table illustrates that J1, in SEQ ID NO 11-14 starts at differing positions and not position 1. For example J1 in SEQ ID 11 is followed by a tetrapeptide GSGC, in SEQ ID NO 14, its is followed by GSPCGTETDFP etc. Based on this, all of the structural requirements are met by the claims.

Applicant arguments have been fully considered but have not been found persuasive.

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While Applicants have provided a table illustrating the sequences and positions of J, this tabular form does not appear in the originally filed specification. Based on the claims, one would read SEQ ID NO 11, 12, 13, 14 as sequences corresponding to formula PI. This formula as claimed does not recite nor imply the presence of amino acids prior to the J1 variable. Thus, one would read that in SEQ ID NO 11-14 J1 corresponds to the first amino acid in the sequence. This is reflected on page 10 of the specification where the sequences are defined generically formula PI. This formula does not mention that J1 is followed by other amino acids. Rather, this formula implies that J1 is the FIRST amino acid in the sequence.

While on page 18, the specification does imply that the N-terminal and/or C-terminal may comprise additional amino acids and on page 19 another formula PII, this is not within the claims. As Applicants well know “[l]imitations appearing in the specification but not recited in the claim should not be read into the claim.” See MPEP 2106. Thus, as claimed in the instant application, SEQ ID NO 11-14 do not correspond to the P1 formula and thus the claims are indefinite.

Rejection is maintained.

2. Claim 34 is allowed.
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on



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the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654